Medication Assisted Treatment Leadership Council
Statement for the Record

House Energy & Commerce Health Subcommittee
Hearing on Combating an Epidemic: Legislation to Help Patients with Substance Use Disorder
March 3, 2020

Chairwoman Eshoo, Ranking Member Burgess, and members of the Subcommittee, thank you for accepting this statement on behalf of the Medication Assisted Treatment Leadership Council (MAT LC). MAT LC is comprised of nearly 300 Opioid Treatment Program (OTP) facilities across 39 states, including nearly 60 in California and 15 in Texas. Our health care teams provide lifesaving care to more than 100,000 patients suffering from opioid use disorder (OUD) every day.

OTPs are highly-regulated, highly-structured, comprehensive treatment programs that provide Medication-Assisted Treatment (MAT). We are subject to rigorous oversight at the federal, state and local levels – including SAMHSA, the DEA, state regulatory and Medicaid authorities and pharmacy boards. Each of our facilities must be continuously accredited by a SAMHSA-approved body.

OTPs have been the gold standard in treating OUD for the past 50 years. OTPs deliver patient-centered, integrated care under one roof. We employ physicians, pharmacists, nurses, counselors, administrators, social workers, and clerical staff to form interdisciplinary treatment teams that provide daily care to patients suffering from OUD. A patient suffering from OUD has access to the full range of MAT services and medications within the OTP setting.

However, it is critical that the Subcommittee understand that medication alone is not treatment. Medication merely helps to stabilize OUD patients, allowing them to receive the behavioral health services that are critical to recovery. OTPs are required, by law, to provide counseling to our patients. Those who are new to treatment or not succeeding in treatment receive more frequent counseling. Our patients are also subject to at least eight random toxicology screens each year. This ensures that medication is being properly used and that illicit drug use is not continuing – both of which help guide clinical decision-making. Lastly, OTPs are required to employ robust anti-diversion measures to protect patients from abusing the medication or selling it on the street.

Conversely, physician office-based opioid treatment (OBOT) programs are largely unregulated and do not offer the full suite of MAT services and supports. Often times, patients only get medication, often buprenorphine, in the OBOT. OBOTs do not have to provide or even refer for counseling, let alone ensuring that patients are actually receiving it. OBOTs are not required to screen patients to ensure they are taking the medication (buprenorphine) they are being prescribed or even that they are abusing opioids. OBOT providers are required to have just eight hours of online training in addiction medicine. Not surprisingly, the only large study of OBOTs concluded that "the quality of care received seemed generally poor."[1] This is not an indictment on these providers so much as it is evidence that they are simply not trained adequately and do not have the requisite resources to deal with complex patients who are suffering from OUD..

In 2000, Congress sought to experiment with expanding OUD treatment to the physician office setting. In exchange for forgoing significant oversight and regulation, Congress rightly placed a limit on the number of OUD patients each OBOT physician could treat (30 in the first year, up to 100 beginning in year 2). These limits were thoughtfully put in place to ensure that these largely unregulated physicians, the vast majority of whom have little training in addiction treatment nor the relationships with mental health providers to ensure patients are actually receiving critical counseling services in conjunction the with buprenorphine they are being prescribed, did not become unregulated addiction treatment practices and potentially pill mills.

In 2018, Congress passed the SUPPORT Act which vastly expanded these patient limits. Physicians can now prescribe up to 275 patients after just eight hours of online training – a 175% increase over the previous limit. This means that, currently, physicians can treat 14 patients PER DAY for opioid addiction if the physician sees each patient just once per month (many of these complicated patients should be seen more frequently than once per month). Two-thirds of the highly specialized OTPs across the country treat FEWER than 200 patients. Simply stated, the current patient limits are already set too high absent additional oversight, quality reporting, and training requirements. OTPs are not subject to patient limits because we are heavily regulated, as any addiction treatment center that prescribes opioids should be.

The SUPPORT Act also allows nurse midwives, nurse anesthetists, and other mid-level clinicians, to prescribe buprenorphine to OUD patients. There is no requirement that these patients receiving counseling for their addiction or that they receive random toxicology screenings. Instead of ensuring patients receive evidence-based treatment present in opioid treatment facilities, Congress opted for a massive expansion of opioid (buprenorphine) prescribing authority in the OBOT setting without any understanding if patients in the OBOT setting were receiving quality care under the previous patient limits.

[1] Gordon, et al, "Patterns and Quality of Buprenorphine Opioid Agonist Treatment in a Large Medicaid Program," Journal of Addiction Medicine, 2015.

Thankfully, Congress commissioned an HHS study, due no later than October 24, 2020, that will include recommendations on where OBOT patient limits should be set. In developing these recommendations, the Secretary is required to examine:

- the average frequency with which qualifying practitioners see their patients;
- the average frequency with which patients receive counseling, including the rates by which such counseling is provided by such a qualifying practitioner directly, or by referral;
- the frequency of toxicology testing, including the average frequency with which random toxicology testing is administered;
- the average monthly patient caseload for each type of qualifying practitioner;
- the treatment retention rates for patients;
- overdose and mortality rates; and
- any available information regarding the diversion of drugs by patients receiving such treatment from such a qualifying practitioner.

The MAT LC firmly believes that Congress should wait to further legislate on the OBOT patient limits before fully considering the findings of the OBOT quality of care report and Secretarial recommendations that it commissioned. That is why **the MAT LC strongly opposes H.R. 2482**, **the Mainstreaming Addiction Treatment Act of 2019**, which would eliminate any OBOT addiction training requirements and allow OBOT physician and practitioners to treat an unlimited number OUD patients without any oversight. If the report shows that patients are indeed receiving regular counseling, that medication is not being diverted, that practitioners can appropriately manage 275 patients, then Congress could consider increasing the patient limits above the 175% increase it passed just 16 months ago. We are confident the study will show nothing is being done to ensure patients are participating in counseling and drug diversion is not being tracked and, therefore, OBOT patients are receiving sub-optimal care and communities are being flooded with diverted opioids, leading to misuse and abuse.

Proponents of H.R. 2482 argue that patient limits do not exist for other diseases. This is true. But consider that OUD patients are extremely complex patients that should be treated by a team of professionals trained in addiction medicine. Nine of the eleven diagnostic criteria for opioid use disorder are behavioral components, just two are physiological (Diagnostic and Statistical Manual of Mental Disorders-V). Would you trust a podiatrist to treat cancer? Would you want a dentist to perform heart surgery? Physicians and surgeons specialize in areas of medicine for a reason. If OBOT providers want to treat an unlimited number of OUD patients, those providers could specialize in this area of medicine and become an OTP and be regulated as such.

Proponents of H.R. 2482 will also note that some foreign countries, like France, do not impose limits on the number of patients receiving buprenorphine. In France, patients can only receive up to seven days of buprenorphine before returning the physician for another prescription. Physicians in France usually request that pharmacists provide daily, supervised dosing of buprenorphine.[2] In the U.S., patients can go up to six months without seeing their physician and still receive refills for their buprenorphine prescription every month. Buprenorphine diversion is also a significant problem in France. "Diversion (i.e., selling or giving away medication) of buprenorphine to the illicit market is also a major concern and has contributed to an extensive black market in some European countries."

Buprenorphine diversion already an issue today in the U.S. In fact, a recent Johns Hopkins study found that "approximately 43% [of those receiving buprenorphine] filled an opioid prescription during the treatment episode and 67% filled at least one prescription opioid following their treatment episode."[3] Given that the effects of prescription opioid pain medication are blocked by buprenorphine, many of these patients are either diverting the buprenorphine they are supposed to be taking as part of their MAT.

The MAT LC is **very concerned about a particular provision in H.R. 2922, the Respond NOW Act**. Specifically, Section 302 of the bill appears to expand the ability to dispense and/or administer methadone in physician offices and outpatient departments for treatment purposes. largely unregulated providers to prescribe methadone for treatment purposes. Methadone, a Schedule II narcotic, is a highly-effective medication if used properly under strict oversight. If misused, it can result in adverse events as the country experienced in the 1990s and early 2000s when prescriptions for methadone were increasingly being written in physician offices to treat pain, arguably the beginning of the current epidemic. OTPs are heavily regulated by numerous federal authorities solely because we administer and dispense methadone. Physician offices and hospital outpatient departments are not subject to similar oversight nor are they experts in treating addiction. Physician offices and hospitals are unequipped to employ anti-diversion programs like those required of OTPs. Unlike physician offices that have resisted or even opposed regulation, OTPs have appreciated that care protocol regulations, which have been developed over many years, have resulted in the best treatment outcomes and very low diversion rates. Consider the following findings from SAMHSA's "Methadone Mortality – A Reassessment" from 2007:

- "Poisoning deaths mentioning methadone increased nearly 400 percent, growing from 4 percent of all poisoning deaths in 1999 to 13 percent of all such deaths in 2004. Poison Center data from 2003-2006 showed that methadone had the highest rate of deaths of patients who were ***prescribed*** the drug, rather than having it dispensed by an Opioid Treatment Program." [emphasis added]

[2] Buprenorphine substitution treatment in France: drug users' views of the doctor-user relationship, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1950347/

[3] http://www.jhsph.edu/news/news-releases/2017/many-patients-receive-prescription-opioids-during-medication-assisted-treatment-for-opioid-addiction.html

- "The RADARS System obtains data on prescription drug abuse from multiple perspectives, including poison centers, key informants, law enforcement, and OTPs. Data from 2002 to 2007 indicate that for those who filled an opioid prescription, methadone accounts for the highest or among the highest rates of abuse, misuse, or diversion. For example, in the 3-year timeframe 2001-2003, data from the DEA show an increase in thefts and loss of all formulations of methadone, although the largest portion involve tablets. (17% liquid [from] OTPs; 84% tablets and diskettes [from] pharmacy)."

- "Today it appears that abuse accounts for only some of all methadone deaths. The others occur in pain patients who are being mismanaged by physicians who lack sufficient knowledge or skills to use methadone in the treatment of pain, or who use the methadone in a manner other than that prescribed."

- "While distribution of all formulations of methadone (liquid, diskette, and tablet) has increased, the greatest growth in distribution [was] the tablet form, which is dispensed through pharmacies. Tablets represented 33 percent of the methadone market, increasing nearly four-fold since 2000, and were distributed to pharmacies (89 percent) followed by hospitals (10 percent). Diskettes represented 24 percent of the market, increasing three-fold since 2000, and were distributed to pharmacies (57 percent) followed by OTPs (41 percent). Since diskettes are only approved for the treatment of addiction and not for pain management, the increased distribution of this form of methadone to pharmacies is considered problematic."

- "Non-OTP treatment providers prescribe more methadone than do OTPs, yet OTPs are subjected to more political pressure and public and media scrutiny than most other types of medical treatment."

As the statistics above clearly show, allowing methadone to be prescribed in the physician offices and prescriptions filled in pharmacies resulted in more death and greater diversion. This should not be surprising because, unlike OTPs, physician offices and pharmacies are not sufficiently regulated nor equipped to handle Schedule II narcotics. We urge that Section 302 be dropped from H.R. 2922. Further, for the reasons stated above, we also recommend that Section 301, which would permanently extend buprenorphine prescribing authority to mid-level clinicians, be dropped from the bill until Congress fully considers the findings in the yet-to-be-released HHS report.

MAT LC also has **concerns about H.R. 2281, the "Easy MAT for Opioid Addiction Act."** While we understand the goal of the legislation, we are certain it will have significant unintended consequences that far outweigh the benefits. By dispensing three days of powerful narcotics to people with acute OUD, the chances that the medication will be misused or abused are substantial. The recipient is likely to either use all the medication at one time, thus leading to overdose and death or sell the medication to support an illicit drug habit. In the OTP setting, patients who are not yet stabilized in their treatment journey are only given one dose per day and that dose must be consumed by the patient in the presence of an OTP professional. Each subsequent dose is treated the same. This helps protect the patients from abusing or diverting the medication. Under H.R. 2281, an at-risk patient could receive three days of medication in just one day. We urge the Subcommittee to reject this well-intentioned by practically-dangerous legislation.

In order to combat the opioid abuse epidemic, the MAT LC urges Congress to make permanent a provision in the SUPPORT Act which requires state Medicaid programs to cover all FDA-approved medication to treat OUD. We also suggest earmarking funds derived from opioid settlements for treatment purposes, including those provided in the OTP setting. Lastly, there is much Congress could do to encourage greater collaboration between providers involved in treating OUD, including funding for programs like Vermont's "hub and spoke" model which connects physician practices (spokes) with OTPs (hubs) to help manage patient care and linking hospitals with OTPs throughout the community.

Thank you for considering our comments today. The MAT LC looks forward to working with the Committee as it seeks to move legislation to combat this deadly disease.

Sincerely,

Alex Dodd
CEO
Aegis Treatment Centers

David White
CEO
BayMark Health Services

Jay Higham
CEO
Behavioral Health Group

Nick Stavros
CEO
Community Medical Services

Francis Sauvageau
CEO
New Season

Mark Hickman
CEO
Western Pacific Med Corp